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The Japanese Version of the Family Dermatology Life Quality Index: translation and validation

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Running title: A Validation Study of Japanese Version of FDLQI

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## ABSTRACT

Skin conditions affect the quality of life (QoL) of patients and their family members. To assess family members' life quality, a quality-of-life questionnaire uniquely designed for family members is necessary. We translated the Family Dermatology Life Quality Index (FDLQI), originally created and validated by Basra et al., into Japanese, and evaluated its reliability and validity. For psychometric evaluations, 150 dermatology patients and their family members were included. The Japanese version of FDLQI showed high test-retest reliability (intraclass correlation coefficient=0.95) and internal consistency reliability (Cronbach's alpha=0.86). FDLQI scores significantly correlated with DLQI scores ( $r=0.58$ ,  $p < 0.01$ , Spearman's rho) and global question (GQ) which measured the patients' skin condition on a visual analogue scale ( $r = 0.36$ ,  $p < 0.01$ ). Family members of patients with inflammatory skin diseases showed higher FDLQI scores than those with isolated lesions, but the difference was not statistically significant ( $5.98 \pm 4.61$ ,  $4.22 \pm 3.52$ , respectively,  $p=0.062$ , Mann-Whitney U-test). Responsiveness to change was demonstrated in a group in which patients' skin condition was assessed as improved ( $n = 37$ ,  $r = 0.46$ ,  $p < 0.01$ ) but not in that in which patient's skin condition became worse. The difference of the change between the two groups was statistically significant ( $p < 0.01$ ). Additionally, the change in FDLQI scores and GQ were significantly correlated ( $r = 0.40$ ,  $p < 0.01$ ). Exploratory factor analysis suggested essential unidimensionality of the instrument. We showed acceptable validity and responsiveness of this Japanese version of FDLQI. Further clinical epidemiological studies are required to confirm this.

Key words: Family, FDLQI, Psychometric evaluations, QoL, Validation, Skin disease

## INTRODUCTION

Many skin diseases influence patients' life quality in various aspects of their lives. The disability of patients can also influence the life quality of patients' family members. The influence can be serious for partners or other family members, as well as the caregivers of children.<sup>1-3</sup> This secondary impact on the quality of life (QoL) of close family members has been shown to be serious in emotional aspects but may also be seen in the physical well-being, social, and financial aspects of their lives.<sup>1,2</sup> Understanding the disability experienced by family members is essential to create educational and supportive programs to improve their life quality.<sup>4</sup> To evaluate their QoL accurately, a comprehensive questionnaire specific for family members is necessary. The Family Dermatology Life Quality Index (FDLQI) is a unique QoL measure designed for family members of

dermatology patients, developed and validated by Basra et al.<sup>5,6</sup> It has been shown to be a practical and useful tool to assess the life quality of family members.

In this study, we translated the FDLQI into Japanese and carried out a psychometric study in Japanese patients and their family members or partners.

## **METHODS**

The study was approved by the Ethical Committees of Tokyo Women's Medical University and Ogikubo Hospital.

### **FDLQI**

The FDLQI is a dermatology-specific QoL instrument for family members of patients with skin disease.<sup>5</sup> It has 10 items asking family members or partners how their QoL (emotional, physical well-being, relationships, people's reaction, social life, leisure activities, burden of care, housework, job/study, and expenditure) over the last 1 month has been affected by the patient's skin disease. Each item can be scored 0(Not at all/Not relevant), 1(A little), 2(Quite a lot), and 3(Very much). Scores for each item (0-3) are totaled for FDLQI score that ranges from 0 to 30. A higher score represents greater impact on QoL.

### **Translation**

Permission to translate the FDLQI into Japanese was given by the authors of the instrument.

The translation was carried out by the forward- and back-translation method. The translators consisted of one non-medical person and two dermatologists, all of whose mother tongue was Japanese. They translated the instrument into Japanese independently, and the translation team then produced a unified translation, the first Japanese version, by consensus. Two bilingual English language experts, a dermatologist and a non-medical person, who were unaware of the original version, carried out back-translations of the first Japanese version independently.

The original authors of the instrument reviewed both of the first back-translations. Forward- and back-translations were repeated to reach the semantic equivalent translations. The intermediate Japanese version was pre-tested in a pilot group composed of adult family members of dermatology patients. They completed the questionnaire and were asked if the translated items were comprehensible. Any items found to be problematic in the pre-testing were refined to generate a final Japanese version of the instrument.

### **Psychometric evaluations**

The psychometric evaluations closely replicated the methodology used in the original study.<sup>5</sup>

Patients and their accompanying family members or partners were recruited at three dermatology out-patient clinics; the Institute of Women's Health, Tokyo Women's Medical University, Tokyo Women's Medical University Medical Center East, and Ogikubo Hospital. Separate information sheets and consent forms were used for the patients and their family members.

On the first visit, the Japanese version of the FDLQI was administered to 150 family members, aged 18 years and older, of dermatology patients with inflammatory diseases (acne, eczema, psoriasis, etc.) or isolated lesions (benign tumors, verruca, pigmented nevus, etc.). The family members were asked to assess the patient's disease severity over the last month using a global question (GQ) which was to measure the patient's skin condition on a visual analogue scale; 0 indicating 'clear' skin and 10 'worst possible'.

The family members were also given another set of FDLQI and GQ, and asked to fill them out one week later and return them by post. Patients (age  $\geq 16$ ) were asked to respond to the Japanese version of the DLQI<sup>7</sup> and GQ. The participant family members who visited the hospital three to six months later were again asked to respond to the FDLQI and GQ.

FDLQI or DLQI questionnaires missing more than one item were excluded from analysis.

Statistical analyses were performed using SPSS version 22.0. Score distribution of the FDLQI and the frequency of the answer to each item were evaluated and ceiling and floor effects were assessed.

For test-retest reliability, only the data in cases with unchanged GQ (not changed by more than one point on the 0-10 scale) after one week were used. The intraclass correlation coefficient (ICC) for each item and for the total scores were calculated.

Internal-consistency reliability was determined with Cronbach's alpha coefficient.

Responsiveness to change was assessed as follows. Family members of patients who visited three to six months after the first visit were asked to report GQ. Cases with improved or worsened GQ (changed by more than one point on the 0-10 scale) were divided into two groups, 'improved' or 'worsened.' In each group the difference of mean FDLQI scores on the two visits was assessed using paired sample t-test.

In addition, the difference of the changes in the FDLQI score between the two groups was assessed using Mann-Whitney U-test.

Correlation between changes in the scores of FDLQI and GQ in both groups was also assessed.

Construct validity was assessed by verifying three *a priori* hypotheses. First, there would be a moderate to high correlation between the QoL of family members and the patients. To

verify this hypothesis, we assessed the correlation coefficient between DLQI scores from the patients (age  $\geq 16$ ) and FDLQI scores from their family members. Second, the degree of the QoL impairment of family members would be related to the patients' disease severity. To verify this hypothesis, we assessed correlation coefficients between FDLQI and GQ scores by family members. Third, QoL of family members of patients with inflammatory dermatoses (such as eczematous dermatitis, urticaria, or acne) would be more impaired than those of family members of patients with isolated lesions (such as naevi, viral warts, or basal cell carcinomas). To verify this hypothesis, we compared FDLQI scores from the two groups using the Mann-Whitney U-test.

To assess unidimensionality of the instrument, exploratory factor analysis was carried out using the maximum-likelihood method with promax rotation. The factors were labelled based on higher values of factor loadings.

## RESULTS

### Translation

During the review of the first back-translations, many expressions in the two back-translations were shown to be problematic and required further forward and back-translations to reach satisfactory agreement with the original instrument. Such items included the expressions corresponding to 'emotional distress' (question 1), 'frustration' (question 1), 'well-being' (question 2), 'bullying' (question 4), 'social gatherings' (question 5), 'recreation/leisure activities' (question 6) in the original English version. To find semantically equivalent Japanese words, the translating team discussed the issues thoroughly and produced the second back-translations. After review of the second back-translations, there were still a few doubtful expressions such as 'emotional distress' in the original version and 'difficulty' in one of the back-translations. In the review of the third and fourth back-translations, only a few linguistic issues in the use of the words were found and required small changes as follows; the word 'QoL' was spelled out in full as 'quality of life', and the words 'visiting or' were added before 'inviting people' (question 5). The fifth back-translations were reviewed and found to be semantically equivalent to the original English version.

The intermediate Japanese version was pre-tested with a pilot group and proved to be comprehensible.

### Psychometric evaluation

One-hundred and fifty family members of dermatological patients responded to the Japanese version of the FDLQI. Among 128 participants who completed and returned a re-

test questionnaire by mail one week later, 57 showed unchanged GQ score and the data from these were processed for test-retest reliability. Ninety-one patients (age  $\geq 16$ ) responded to the Japanese version of the DLQI. After three to six months, 79 family members responded to the Japanese version of FDLQI. Among them 37 family members showed improved GQ score and 6 family members showed worsened GQ score compared to the baseline.

Demographic details are shown in Table 1. The age of family members was from 22 to 95 years with a mean age of 48.0 years. Most of them were women. In addition, most were parents of patients. The patients had been diagnosed with one of the skin conditions listed in Table 2.

Score distribution of FDLQI ranged from 0 to 21 (median = 3.0, mean = 5.63, SD = 5.44), indicating there was no ceiling effect. Concerning floor effect, 5.3% of the subjects scored 0.

Figure 1 shows the percentage of answers to individual items. The most frequently reported problem was emotional impairment (84.1%). Other frequently reported problems were burden of care and physical well-being.

Test-retest reliability was assessed by ICC using FDLQI scores of 57 participants (38.0%) with unchanged GQ. The value of ICC for the total score was 0.95 and for the individual items ICC was ranged from 0.74 to 0.94, indicating reproducibility of the scale.

The Cronbach's alpha of the scale was 0.86 and this was not significantly changed by deleting individual items (0.83-0.85). These results indicated that the scale's internal consistency was adequate and that all the items of the scale contributed to the total score. All item-to-total score correlations were significant at  $p < 0.01$ . The correlation coefficients ranged from 0.55 to 0.76.

Concerning construct validity, three *a priori* hypotheses were evaluated. First, there was significant positive correlation between FDLQI scores and patients' DLQI scores ( $r = 0.58$ ,  $p < 0.01$ ) in 90 pairs of family members and patients (age  $\geq 16$ ). Second, the FDLQI score was significantly correlated with disease severity (GQ) of patients assessed by family members ( $r = 0.36$ ,  $p < 0.01$ ). Third, the mean FDLQI scores among families of patients with inflammatory diseases (mean =  $5.9 \pm 4.6$ ,  $n = 119$ ) were higher than those among families of patients with isolated lesions (mean =  $4.3 \pm 3.5$ ,  $n = 28$ ) but the difference was not statistically significant ( $p = 0.09$ ).

Concerning responsiveness to change, the mean FDLQI score in the 'improved' group ( $n = 37$ ) decreased significantly from 7.4 to 3.5 (mean change = 3.8, SD = 4.2,  $p < 0.01$ ). GQ score decreased from 6.5 to 2.3 (mean change = 4.1, SD = 1.7). In the 'worsened' group ( $n = 7$ ), the mean FDLQI score increased from 4.3 to 5.3 (mean change = 1.0, SD = 2.6) but

the difference was not statistically significant ( $p = 0.35$ ). GQ score increased from 2.3 to 5.2 (mean change = 2.9, SD = 1.0). The difference of the change between the two groups was statistically significant ( $p < 0.01$ ). In addition, the change in FDLQI scores and GQ were significantly correlated ( $r = 0.40$ ,  $p < 0.01$ ).

The model of the factor analysis was examined by a chi-square test and shown to be adequately fitted to the data ( $p = 0.296$ ). As shown in Figure 2, the line of the scree plot after the first factor was relatively flat, suggesting that the first factor accounts for most of the variance. After promax rotation, two factors were extracted by retaining those factors with eigenvalues  $> 1$ . The two factors were correlated ( $r = 0.61$ ). The first factor had an eigenvalue of 4.45 and accounted for 44.5% of the common variance, and the second smaller factor had an eigenvalue of 1.10 and accounted for 11.0% of the common variance. The percentage of variance explained by the first factor (44.5%) supported the presence of a dominant single underlying dimension.<sup>8,9</sup> The ratio of the two factors was 4.04, higher than a critical value, i.e. 4.<sup>5</sup> The pattern of eigenvalues was similar to that of the original instrument.<sup>5</sup> These findings supported that the instrument was essentially unidimensional as in the original version.<sup>5,8,9</sup> Essential unidimensionality describes the existence of a single dominant factor and also other relatively minor factors. Factor loadings of the items on two components after promax rotation are shown in Table 3. The two factors were labelled as 'bio-psycho-social factor'; impact on emotional, physical well-being, relationships, and people's reaction, and 'daily activities'; impact on social life, leisure activity, burden of care, and job/study.

## DISCUSSION

In this study, we describe the development of a Japanese version of FDLQI semantically equivalent to the original English version. Psychometric evaluation was carried out on this Japanese version of the FDLQI.

From the score distribution of the Japanese version, no ceiling effect was observed. Only 5.3% of participants scored 0; therefore, the floor effect was small. As far as we know, there has not been a definite standard of ceiling or floor effects for health status questionnaires. McHorney et al. proposed measurement standards for health status questionnaires for individual patient application in clinical practice.<sup>10</sup> According to their criteria, a proposed standard for floor or ceiling effects in the instruments should be less than 15%; this criterion has been supported by other researchers.<sup>11,12</sup>

Cronbach alpha was 0.86 and similar to that of the original version (0.88), Italian version (0.89) and Persian version (0.87).<sup>5,13,14</sup> The minimum acceptable level of Cronbach's alpha is generally thought to be 0.7, and the values between 0.7 and 0.9 suggest a good internal



consistency.<sup>15,16</sup> Alpha was not increased when each item was deleted. Therefore, every item was considered to be essential.

All item-to-total score correlations were significant and these results confirmed reliability of the Japanese version. Construct validity was not fully confirmed because one of the three *a priori* hypotheses was unable to be proven at a statistically significant level.

Concerning responsiveness to change, significant correlation was observed between the changes of FDLQI scores and GQ scores in the group in which GQ scores improved at three to six months after the first visit though in the group in which the participants assessed GQ score worse, correlation was not significant. The reason was probably because of the small number of patients. In addition, the change in FDLQI scores between the two groups was different at a statistically significant level. Furthermore, the change in FDLQI scores and GQ were significantly correlated. These results suggest that the Japanese version of the FDLQI responds to change; though further study is necessary to fully confirm that.

From the results of the factor analysis, there were two factors with eigenvalues > 1. However, the pattern of eigenvalues of the Japanese version of FDLQI was similar to that of the essentially unidimensional original version which implies an underlying single dominant factor.<sup>5</sup> Accordingly it is reasonable to add the scores of the 10 items to obtain a total score in the Japanese version of FDLQI.

In this psychometric study of the Japanese version of FDLQI, we confirmed the acceptable validity and responsiveness including test-retest reliability, internal consistency, and the absence of problematic floor or ceiling effects of the FDLQI score.<sup>10,11,12</sup> In addition, we believe the scale should be treated as a unidimensional one, since the total score of the 10 items is taken as a whole as in the original instrument. To confirm more accurately the responsiveness to change and construct validity, further clinical epidemiological studies are required.

FDLQI has been translated into many languages.<sup>17</sup> In addition to validation studies on groups of various skin diseases, the impact of specific skin diseases on patients' family members' QoL has been investigated.<sup>4,13,18,19,20</sup> The QoL of family members of vitiligo patients showed a mean FDLQI score of 10.3 and their lives were shown to be affected in various aspects.<sup>4</sup> Caregivers of patients with epidermolysis bullosa showed a mean FDLQI score of 9.8, and their QoL was impaired, especially in burden of care followed by emotional aspect.<sup>13</sup> In addition, FDLQI scores were found to be higher in caregivers of patients whose age was between 10 and 20.<sup>13</sup> Family members living with leg ulcer patients also showed highly affected QoL and their mean FDLQI score was reported to be 14.4 and clearly related to the patients' QoL.<sup>18</sup> In this study, no cases of vitiligo, leg ulcers,

or epidermolysis bullosa were included. It would be interesting to know the secondary impact of such skin diseases on the life quality of Japanese patients' family members. Martinez-Garcia et al. recently analyzed the QoL of individuals who live with psoriasis patients and showed that their FDLQI scores were strongly influenced by the patients' DLQI scores.<sup>19</sup> It would be interesting to study how QoL of Japanese psoriasis patients would be related to their family members' life quality. Caregivers of children with atopic dermatitis have impaired QoL in their emotional and social aspects of life.<sup>3</sup> Chernyshov et al. studied the impact of atopic dermatitis on caregivers of children under the age of four using FDLQI and reported that the parents' mean FDLQI score was 11.8 and emotional distress was the highest score item.<sup>20</sup> In our study, there were five caregivers of children under the age of four. Their mean FDLQI score was 5.8 and the highest score was observed in emotional distress. These findings suggest that Japanese caregivers for children with atopic dermatitis might be influenced similarly in their emotional aspect but the degree of the impact might be less serious, though further studies on larger groups of patients are of course necessary.

From these studies, impairment of family members' life quality might be closely influenced by patients' nature of skin condition, age and QoL.<sup>4,13,18,19,20</sup> To measure family members' life quality adequately and accurately, a combination use of skin disease-specific and dermatology-specific measures would be recommended.<sup>20</sup> The Japanese version of FDLQI could be applied to a variety of skin diseases and it would be a useful tool to evaluate the impact of skin diseases on QoL of family members of dermatology patients.

## LIMITATION

In this study, the effects of sociodemographic aspects of participants were not assessed. Eczema accounted for a relatively high proportion of the diagnoses because the Institute of Women's Health has a very high concentration of eczema patients. The other limitation is disproportionate representation of gender, as there were approximately twice as many female participants as male participants.

**CONFLICT OF INTEREST:** AY Finlay and MKA Basra are joint copyright owners of the FDLQI. AY Finlay is joint copyright owner of the DLQI: Cardiff University and AYF receive royalties from its use.

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#### Legends to figures

Figure 1 Percentage of the answers to the individual items of the FDLQI.

Figure 2 Scree plot of different components of the FDLQI showed that the line after the first factor was almost flat.

**Table1 Demographic characteristics of study participants (n=150)**

<b>Patients</b>		
<b>Gender (%)</b>		
Males		50 (33)
Females		100 (67)
<b>Age (years)</b>		
Mean (SD)		31.2 (28.0)
Range		1–95
<b>Family members/Partners</b>		
<b>Gender (%)</b>		
Males		20 (13)
Females		130 (87)
<b>Age (years)</b>		
Mean (SD)		48.0 (14.7)
Range		22–95
<b>Relationship to patient (%)</b>		
Parent		97 (64.7)
Spouse/Partner		37 (24.7)
Son/Daughter		15 (10.0)
Grandchild		1 (0.7)

**Table 2** Dermatological diagnoses of patients (n=150)

<b>Inflammatory(%)</b>	
Eczema	70(46.7)
Urticaria	10(6.7)
Acne	7(4.7)
Drug eruption	4(2.7)
Prurigo	4(2.7)
Herpes zoster	2(1.3)
Tinea	2(1.3)
Hyperhidrosis	2(1.3)
Others	18(12.0)
<b>Total</b>	<b>119(79.3)</b>
<b>Isolated lesions(%)</b>	
Benign skin tumors	14(9.3)
Naevi	10(6.7)
Squamous cell carcinoma	2(1.3)
Others	2(1.3)
<b>Total</b>	<b>28(18.7)</b>
<b>Others(%)</b>	
Trichotillomania	3(2.0)
<b>Total</b>	<b>3(2.0)</b>

**Table 3** Factor loadings of the 10 items on two components

<b>FDLQI item</b>	<b>1</b>	<b>2</b>
<b>Emotional</b>	<b>0.75</b>	<b>0.36</b>
<b>Physical well-being</b>	<b>0.83</b>	<b>0.53</b>
<b>Relationships</b>	<b>0.72</b>	<b>0.54</b>
<b>People's reaction</b>	<b>0.48</b>	<b>0.46</b>
<b>Social life</b>	<b>0.46</b>	<b>0.78</b>
<b>Leisure activities</b>	<b>0.42</b>	<b>0.82</b>
<b>Burden of care</b>	<b>0.53</b>	<b>0.58</b>
<b>House work</b>	<b>0.50</b>	<b>0.51</b>
<b>Job/ Study</b>	<b>0.47</b>	<b>0.60</b>
<b>Expenditure</b>	<b>0.42</b>	<b>0.40</b>



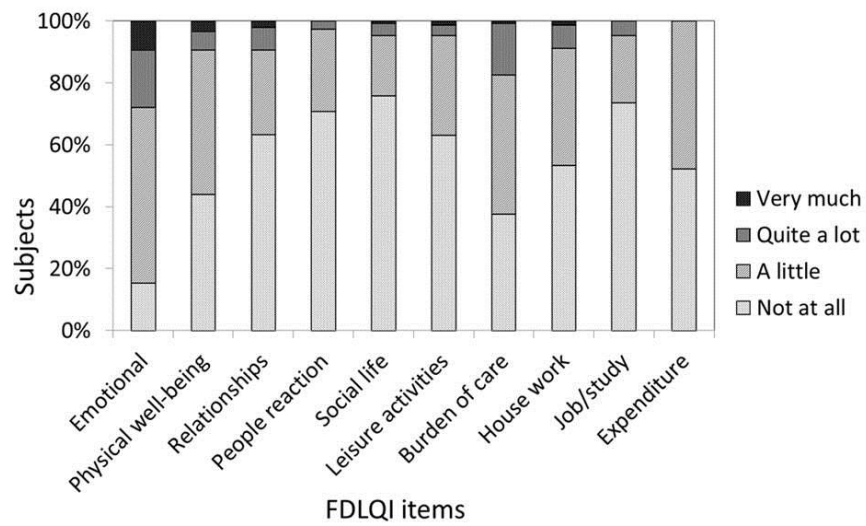


Figure 1 Percentage of the answers to the individual items of the FDLQI.

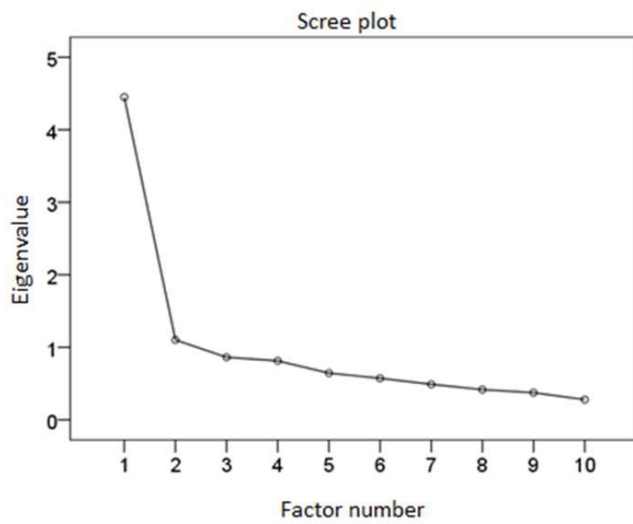


Figure 2 Scree plot of different components of the FDLQI showed that the line after the first factor was almost flat.